

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Spot-On CY

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Cyhalothrin 2.0 %w/v

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Spot on solution

Clear amber coloured solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

As a topical application for the control of lice and flies on cattle.

On cattle: for the control of both sucking and biting lice, including *Damalinia bovis*, *Solenopotes capillatus*, *Linognathus vituli* and *Haematopinus eurysternus* on all ages of cattle.

Also as an aid in the control of both biting and nuisance flies including *Haematobia irritans*, *Stomoxys calcitrans*, *Musca* species and *Hydrotaea irritans*.

4.3 Contraindications

None.

4.4 Special warnings for each target species

In some calves less than six months of age which received a 10 ml dose, transient signs of mild irritation have been seen 24 hours after treatment.

4.5 Special precautions for use

Special precaution(s) for use in animals

There are no special precautions recommended.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

A transient tingling sensation on the skin may occur if cyhalothrin comes in contact with the face of some individuals.

It is advisable that the following precautions should be observed:

Wear protective gloves when applying the product or when handling recently treated animals.

Remove heavily contaminated clothing immediately and wash before re-use.

Wash splashes from skin immediately with soap and plenty of water.

Wash hands and exposed skin before meals or smoking and after work.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

In case of accidental ingestion, wash out mouth with water and seek medical advice.

4.6 Adverse reactions (frequency and seriousness)

Minor signs of discomfort have been seen in some cattle during the 48 hours after treatment. This is of no long term detriment to the animal.

In some calves less than 6 months of age which received a 10 ml dose, transient signs of mild irritation were seen 24 hours after dosing.

4.7 Use during pregnancy, lactation or lay

No special precautions are recommended.

4.8 Interaction with other medicinal products and other forms of interaction

Do not mix any other insecticide or acaricide with the product.

4.9 Amounts to be administered and administration route

For topical administration at a dosage of 1–2 mg/kg.

DOSAGE

Cattle: 10 ml

ADMINISTRATION

Apply a single dose with the special "squeeze 'n pour" dispenser pack or the Coopers Spot On applicator gun on one spot on the mid–line of the pack at the shoulders as directed on dispenser or applicator pack.

Lice on cattle:

One application will usually eradicate all lice. Complete clearance of all lice may take 4–5 weeks during which time lice hatch from the eggs and are killed. A very few lice may survive on a small minority of animals, therefore it may be necessary to re–treat these animals 6 to 8 weeks later.

Flies on cattle:

To control biting and non–biting flies, treatment should be repeated as necessary. Frequency of treatment will depend on numbers and species of flies present. Normally good control of face flies and stable flies can be expected for 2 weeks or more. Where horn flies predominate, good control can be expected for 4–6 weeks. Re–treat as necessary. Fly challenge is highest in hot, humid weather and is also increased by the availability of fly breeding sites such as stagnant pools, rotting vegetation, etc.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Cattle treated with 3 x the recommended dose showed no signs of adverse effects.

4.11 Withdrawal Period(s)

Cattle intended for human consumption may only be slaughtered from 14 days after the last treatment.

Milk for human consumption may only be taken from cows from 72 hours (that is, from the 6th milking) after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet code QP 53 AC 06

5.1 Pharmacodynamic properties

Cyhalothrin is a synthetic pyrethroid possessing pesticidal activity. It is one of a large family of pyrethroid esters which have evolved as synthetic analogues of the original insecticidal extracts isolated from powdered pyrethrum flowers. Cyhalothrin belongs to the second generation of pyrethroids in which overall stability of the molecule is improved with correspondingly increased resistance to photo- and biodegradation and enhanced insecticidal activity, similar to the stabilised alpha-cyano pyrethroids. Like deltamethrin, it is more potently toxic to insects and acarines, because of the slower rate of metabolism.

The precise mode of insecticidal activity of pyrethroids remains uncertain but they are potent neurotoxins in insects, causing failure in sensory co-ordination and disorganised motor activity, hence the “knock-down” effect. Pyrethroids are metabolised by the oxidative and hydrolytic pathways far more rapidly in mammals, so that neurotoxic effects only occur at dosages which are many orders of magnitude greater than those required for pesticidal activity. Pharmacologically, cyhalothrin is relatively inert in mammalian systems.

5.2 Pharmacokinetic properties

Cyhalothrin is rapidly metabolised. Metabolism is qualitatively similar in farm animals and similar to the metabolism of the compound by rats and dogs. In all species metabolism is extensive and consists of cleavage of the ester linkage. In farm animals treatment by the oral and topical routes gives a similar pattern of metabolites in tissues.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Volatile cyclomethicone oil

Maize oil (dewaxed)

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale : 3 years

6.4 Special precautions for storage

Store below 25°C in original container away from food, drink and animal feeding stuffs.

Keep container tightly closed.

6.5 Nature and composition of immediate packaging

250 ml, 500 ml and 1 litre natural high density polyethylene squeeze and pour bottles with integral dose-measurement and 1 litre flexi-pack container.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Dangerous to fish and other aquatic animals. Do not contaminate ponds, waterways or ditches with the product or used container.

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Pfizer Healthcare Ireland,
Trading as: Pfizer Animal Health,
Ringaskiddy,
Co. Cork,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10019/113/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16th October 2007

10 DATE OF REVISION OF THE TEXT

16th November 2011